

Claim 1 recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a pharmaceutically active ingredient and a matrix comprising directly compressible dextrose monohydrate and sucralose. The tablet contains less than 5% fat and said matrix is substantially free of non-saccharide, water-soluble polymeric binders.

Claim 12 also recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a pharmaceutically active ingredient and a matrix comprising directly compressible dextrose monohydrate and sucralose. The matrix also comprises at least one disintegrating agent selected from microcrystalline cellulose, starch, sodium starch glycolate, crosslinked polyvinylpyrrolidone, crosslinked carboxymethylcellulose, and mixtures thereof; at least one lubricant selected from magnesium stearate, stearic acid, and mixtures thereof; and optionally an auxiliary ingredient selected from fillers, sweeteners, surfactants, glidants, acidulents, antioxidants, preservatives, coloring, flavoring agents, and mixtures thereof. The tablet is substantially free of triglycerides and said matrix is substantially free of non-saccharide, water-soluble polymeric binders.

Claims 1-13 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,684,534 to Valentine in view of U.S. Patent No. 4,327,076 to Puglia. The Examiner argues that Valentine teaches a chewable tablet comprising active ingredients, dextrose monohydrate and sucrose. The Examiner acknowledges that Valentine does not teach the use of sucralose, but argues that it would be an obvious variation to substitute sucralose for sucrose. Puglia is cited for a teaching of a compressed tablet containing fats in the range of 2 to about 45%.

Applicants respectfully request reconsideration of this rejection. Valentine discloses a tablet having a harder outer shell and a softer interior. The tablet may be made by direct compression and comprises an active ingredient and agglomerate. The agglomerate in turn comprises a carbohydrate selected from the group consisting of dextrose, dextrose monohydrate, maltodextrin, fructose, sucrose, lactose, maltose, and xylose held together by a small, critical amount of water soluble binder selected from the group consisting of maltodextrin, corn syrup solids, dextrose, sucrose, polyvinylpyrrolidone, and cooked starch paste.

As recognized by the Examiner, Valentine does not teach or suggest the use of sucralose, which is required by the claimed invention. Moreover, sucralose and sucrose are not readily interchangeable. Sucrose is a bulk sweetener having a relative sweetness index of

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1. Sucralose is a high intensity sweetener having a relative sweetness index of 600, making it 600 times sweeter than sucrose. It would therefore not be obvious to substitute one for the other. When compressed, dextrose monohydrate/sucrose particles would have a much different taste than dextrose monohydrate/sucralose particles.

It should also be noted that neither Valentine nor Puglia teach or suggest applicants' recitations that the claimed tablet contain less than 5% fat or that the matrix be substantially free of non-saccharide, water soluble polymeric binders. The Examiner attributes no patentable distinction to these features. However, neither reference teaches or suggests these features, which represent unexpected advantages in the claimed tablet. As stated in the specification on page 4, formulations with little or no fat are more stable at elevated temperatures, eliminating the need for specially controlled shipping and storage conditions. Fats are susceptible to oxidative and chemical hydrolysis, leading to a "rancid" taste and/or odor.

For these reasons, the claimed invention is patentable over Valentine and Puglia, alone or in combination. Reconsideration of the application is therefore requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 13 has been rewritten as follows:

13. The tablet of claim ~~13~~12 wherein the tablet comprises no more than 25 % by weight of said optional auxiliary ingredients.